

Appl. No. 10/084,587

Request for Reconsideration dated February 17, 2005
Reply to Office Action of August 18, 2004

PATENT

REMARKS/ARGUMENTS

This Request for Reconsideration is responsive to the Office Action mailed on August 18, 2004. A Petition for a 3-month extension of time and an RCE (request for continued examination) are attached.

Applicants thank Examiner Lau for the courtesy of the personal interview held with the undersigned attorney and Mr. John Storella at the Patent Office on February 9, 2005.

Claims 1-40 stand provisionally rejected under the judicially created doctrine of double patenting over co-pending patent application 09/999,081. Applicants point out that this application has issued as U.S. patent 6,675,104. Applicants acknowledge this rejection and request the Examiner to allow Applicants to finally address it after the claims are found otherwise allowable.

All claims except 16, 20 and 36 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,558,902 to Hillenkamp. Applicants respectfully traverse the rejection.

Regarding claim 1, the Examiner stated that Hillenkamp disclosed a method comprising both steps (a) and (b) of claim 1. In particular, the Examiner stated that Hillenkamp showed the elements of step (a) at, among other places, columns 43-45, column 71, column 69 and columns 4-5. The Examiner stated further that Hillenkamp showed step (b) at columns 44-45. However, Applicants believe that Hillenkamp fails to show several elements of the invention.

Claim 1 is directed to a method of creating a classification model that can discriminate between classes representing different biological status based on data generated by laser desorption mass spectrometry from samples belonging to the classes. So, for example, blood samples from two biological state classes – cancer and non-cancer – are subjected to laser desorption/ionization time-of-flight mass spectrometry to generate mass spectra from the samples. Claim 1 recites that data obtained from these mass spectra are entered into a digital computer. Then, using a classification process, e.g., a classification algorithm such as classification and regression tree analysis (CART), the computer forms a classification model

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that uses the mass spectrometry data to discriminate between the two classes, e.g., that discriminates cancer versus non-cancer based on a mass spectrum. Classification models generated in this way are useful for creating, among other things, diagnostic tests of disease. In such a diagnostic test, a sample from a patient would be subject to mass spectrometry analysis and a classification model would analyze the mass spectrometry data to assign the patient sample into one of the classes, e.g., cancer or non-cancer.

Hillenkamp, in contrast, discloses, generally, methods of detecting nucleic acids by laser desorption/ionization mass spectrometry. It does not disclose the analysis of multiple mass spectra for the generation of a classification model. For example, Hillenkamp columns 43-44 discuss various parameters in mass spectrometry that one can vary in the process of generating a mass spectrum, such as pulse duration and field strength. Column 71 refers to "reactive groups" apparently used to bind a nucleic acid analyte to a probe for mass spectrometry. Column 69 provides a laundry list of viruses that Hillenkamp says can be detected by mass spectrometry. Among those viruses listed are the agents of non-A-non-B hepatitis, class 1 and class 2. However, the patent does not discuss comparing spectra from class 1 and class 2 viruses and developing a classification model to distinguish them. Column 44 also provides general information about mass spectrometry such as types of mass spectrometry and methods for focusing ions (delayed extraction).

Therefore, Hillenkamp did not show every element of step (a) of the claimed method, because it fails to show the entry of data from a plurality of mass spectra from samples of different biological state classes into a digital computer. The reference also failed to show the elements of step (b) because it did not show the generation of a classification model in a computer using this data. Nor is there any suggestion in Hillenkamp to do so. Therefore, Hillenkamp did not anticipate (or obviate) claim 1.

Similarly, Hillenkamp did not anticipate (or obviate) claim 35. Claim 35 is directed to a software product that contains code that executes the method of claim 1. Because Hillenkamp did not anticipate (or obviate) claim 1, it also did not show software that executes the method of claim 1. Therefore, Hillenkamp did not anticipate claim 35 of the invention.

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Regarding the claims that depend from claim 1 or claim 35, because Hillenkamp did not anticipate independent claims 1 or 35, for the reasons stated above, it could not have anticipated claims that depend from these claims.

For these reasons, Applicants request the Examiner to withdraw the anticipation rejection.

The Examiner also objected to claims 16, 20 and 36 as allowable if re-written in independent form. Applicants thank the Examiner for recognizing the patentability of these claims. However, Applicants submit that because the claims from which they depend are not anticipated by Hillenkamp, there is no need to re-write these claims in independent form.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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